ALUMINA, MAGNESIA, AND SIMETHICONE- alumina, magnesia, and simethicone suspension
VistaPharm, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Alumina, Magnesia, and Simethicone Oral Suspension
Maximum Strength

Drug Facts

Active ingredients

(in each 30 mL dose)

Aluminum hydroxide 2400 mg

(equivalent to dried gel, USP)

Magnesium hydroxide 2400 mg

Simethicone 240 mg

Purposes

Aluminum hydroxide.....Antacid

(equivalent to dried gel, USP)

Magnesium hydroxide.....Antacid

Simethicone.....Antigas

Uses

relieves:

- heartburn
- sour stomach
- acid indigestion
- the symptoms referred to as gas

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacid may interact with certain prescription drugs.

When using this product

- do not take more than 60 mL (2 doses) in a 24-hour period
- do not use the maximum dosage for more than 2 weeks except under the advice and supervision of a doctor

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- shake well before use
- adults and children 12 years and older: 30 mL (1 dose) up to 2 times a day or as directed by a doctor
- children under 12 years of age: ask a doctor

Other information

- **each 30 mL contains:** magnesium 990 mg, sodium 30 mg
- store at 20-25°C (68-77°F)
- protect from freezing
- keep tightly closed
- **tamper-evident: do not use if foil on cup is missing or torn**

Inactive ingredients

benzyl alcohol, butylparaben, carboxymethylcellulose sodium, flavor (contains alcohol), hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

Questions or comments?

Call 1-888-655-1505

How Supplied

Alumina, Magnesia, and Simethicone Oral Suspension is a white suspension supplied as follows:

NDC 66689-061-01: 30 mL unit-dose cup
NDC 66689-061-99: Case contains 100 unit-dose cups of 30 mL (NDC 66689-061-01), packaged in 10 trays of 10 unit-dose cups each.

Distributed by:
VistaPharm Inc.
Largo, FL 33771, USA

VP2526
08/20

Principal Display Panel

MAXIMUM STRENGTH

Alumina, Magnesia, and

Simethicone Oral Suspension

each 30 mL contains:

Aluminum Hydroxide Gel……2400 mg

Magnesium hydroxide…….2400 mg

Simethicone……..240 mg

Alcohol 0.5%

Delivers 30 mL

Store at 20°-25°C (68°-77°F) Shake Well

Distributed by:

VistaPharm

Largo, FL 33771, USA

VP2183

Rev.06/20

NDC 66689-061-01

ALUMINA, MAGNESIA, AND SIMETHICONE

alumina, magnesia, and simethicone suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66689-061
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	2400 mg in 30 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	2400 mg in 30 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	240 mg in 30 mL

Inactive Ingredients	
Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
May contain	**ALCOHOL** (UNII: 3K9958V90M)	

Product Characteristics			
Color	WHITE (white suspension)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66689-061-99	100 in 1 CASE	09/30/2020	
1	NDC:66689-061-01	30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part331	09/30/2020	

Labeler - VistaPharm, Inc. (116743084)

Revised: 9/2020 VistaPharm, Inc.